13406-008WOU1

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference FOUNDRY019VP	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US2008/060940	International filing date *(day/month/year)* 18 April 2008	(Earliest) Priority Date *(day/month/year)* 19 April 2007
Applicant THE FOUNDRY, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**.

a. the figure of the **drawings** to be published with the abstract is Figure No. 4

☐ as suggested by the applicant

☒ as selected by this Authority, because the applicant failed to suggest a figure

☐ as selected by this Authority, because this figure better characterizes the invention

b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/060940

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 18/00 (2008.04)
USPC - 606/41
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 18/00, 18/12, 18/14, 18/18, 18/20; A61N 1/28, 1/40, 5/02, 5/04 (2008.04)
USPC - 606/33, 41; 607/101-102, 104, 156

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
MicroPatent

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2004/0210214 A1 (KNOWLTON) 21 October 2004 (21.10.2004) entire document	1, 9, 24, 26 --- 2-6, 12, 13, 17, 18, 20-22, 25
X --- Y	US 2006/0271028 A1 (ALTSHULER et al) 30 November 2006 (30.11.2006) entire document	7, 10, 11, 14-16, 23 --- 6, 8, 12, 13, 17, 19, 20
X --- Y	US 2007/0060989 A1 (DEEM et al) 15 March 2007 (15.03.2007) entire document	27 --- 8
Y	US 6,208,903 B1 (RICHARDS et al) 27 March 2001 (27.03.2001) entire document	2-5, 18, 19, 21, 22, 25

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 August 2008	27 AUG 2008
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2005)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: DANIEL ALTMAN
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* 27 AUG 2008	
Applicant's or agent's file reference FOUNDRY019VP	**FOR FURTHER ACTION** See paragraph 2 below
International application No. PCT/US2008/060940	International filing date *(day month year)* 18 April 2008
Priority date *(day month year)* 19 April 2007	
International Patent Classification (IPC) or both national classification and IPC IPC(8) - A61B 18/00 (2008.04) USPC - 606/41	
Applicant THE FOUNDRY, INC.	

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Date of completion of this opinion 19 August 2008	Authorized officer: Blaine Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (April 2007)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2008/060940

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   [X] the international application in the language in which it was filed.

   [ ] a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. [ ] This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. type of material

      [ ] a sequence listing

      [ ] table(s) related to the sequence listing

   b. format of material

      [ ] on paper

      [ ] in electronic form

   c. time of filing/furnishing

      [ ] contained in the international application as filed

      [ ] filed together with the international application in electronic form

      [ ] furnished subsequently to this Authority for the purposes of search

4. [ ] In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
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Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	2-6, 8, 12-13, 17-22, 25	YES
	Claims	1, 7, 9-11, 14-16, 23-24, 26-27	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-27	NO
Industrial applicability (IA)	Claims	1-27	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1, 9, 24 and 26 lack novelty under PCT Article 33(2) as being anticipated by Knowlton.
Referring to claim 1, Knowlton disclose a system for the application of microwave energy to a tissue (abstract), comprising: a signal generator (22) adapted to generate a microwave signal having predetermined characteristics (para. 0151; para. 0121; claim 7; para. 0261); an applicator (12) connected to the generator (22) and adapted to apply microwave energy to tissue (para. 0108; para. 0121), the applicator (12) comprising one or more microwave antennas (para. 0150) and a tissue interface (21); a vacuum source (13") connected to the tissue interface (fig. 2B; para. 0109; para. 0110, wherein it is disclosed that "pressure source 13" can be a pump, such as a peristaltic pump" and wherein peristaltic pumps are positive displacement pumps which are a type of vacuum pump); a cooling source (15) connected to said tissue interface (21; fig. 2B; para. 0111); and a controller (54) adapted to control the signal generator, the vacuum source, and the coolant source (para. 0170-0172).

Referring to claim 9, Knowlton disclose an apparatus for delivering microwave energy to a target region in tissue (abstract), the apparatus comprising: a vacuum chamber (13") adapted to elevate tissue including the target region (9") and bring the tissue into contact with a cooling plate (fig. 2B; para. 0109; para. 0110, wherein it is disclosed that "pressure source 13" can be a pump, such as a peristaltic pump" and wherein peristaltic pumps are positive displacement pumps which are a type of vacuum pump; para. 0112), wherein the cooling plate (21) is adapted to contact a skin surface above the target region (fig. 1; fig. 2B), cool the skin surface (para. 0099, wherein it is disclosed that "energy can be delivered coupled with topical cooling"), and physically separate the skin tissue from the microwave energy delivery device (fig. 2B, wherein the cooling plate/interface 21 separate the microwave energy delivery device 18 from the skin surface); and a microwave antenna (para. 0150) configured to deliver sufficient energy to the target region to create a thermal effect (para. 0121; para. 0150; para. 0108; abstract; para. 0099).

Referring to claim 24, Knowlton discloses a method of raising the temperature of at least a portion of a tissue structure located below an interface between a dermal layer and subdermal layer in skin (para. 0099-0100), the dermal layer having an upper portion adjacent an external surface of the skin and a lower portion adjacent a subdermal region of the skin (fig. 1; para. 0103), the method comprising the steps of: radiating the skin with microwave energy having a predetermined power, frequency and e-field orientation (12; para. 0108; para. 0121; para. 0151; claim 7; para. 0261); generating a peak energy density region in the lower portion of the dermal layer (para. 0099); initiating a lesion in the peak energy density region by dielectric heating of tissue in the peak energy density region (para. 0099; para. 0239; para. 0225; para. 0015); enlarging the lesion (para. 0239), wherein the lesion is enlarged, at least in part, by conduction of heat from the peak energy density region to surrounding tissue (para. 0239; para. 0225; para. 0015); removing heat from the skin surface and at least a portion of the upper portion of the dermal layer (para. 0111); and continuing to radiate the skin with the microwave energy for a time sufficient to extend the lesion past the interface and into the subdermal layer (para. 0171; para. 0258; para. 0225; para. 0015).

Referring to claim 26, Knowlton discloses a method of controlling the application of microwave energy to tissue (abstract), the method comprising the steps of: generating a microwave signal having predetermined characteristics (para. 0151; para. 0121; claim 7; para. 0261); applying the microwave energy to tissue (para. 0108; para. 0121), through a microwave antenna (para. 0150) and a tissue interface (21) operably connected to the microwave antenna (12; para. 0150; 21; fig. 2B); supplying a vacuum pressure (13") to the tissue interface (fig. 2B; para. 0109; para. 0110, wherein it is disclosed that "pressure source 13" can be a pump, such as a peristaltic pump" and wherein peristaltic pumps are positive displacement pumps which are a type of vacuum pump); and supplying cooling fluid (15) to the tissue interface (21; fig. 2B; para. 0111).

Claims 7, 10, 11, 14-16 and 23 lack novelty under PCT Article 33(2) as being anticipated by Altshuler et al.
Referring to claim 7, Altshuler et al. disclose an apparatus for delivering microwave energy to target tissue (abstract; para. 0058), the apparatus comprising: a tissue interface (fig. 1, wherein the contact plate 8 contacts the tissue 31 at the interface); a microwave energy delivery device (1; para. 0079, wherein it is disclosed that "energy source 1 may be any suitable electromagnetic radiation, EMR, source"; para. 0058); a cooling element (4) positioned between the tissue interface (fig. 1, wherein the contact plate 8 contacts the tissue 31 at the interface) and the microwave energy device (1), the cooling element comprising a cooling plate (8) positioned at the tissue interface (fig. 1, wherein the contact plate 8 contacts the tissue 31 at the interface); and a cooling fluid (para. 0096) positioned between the cooling element (4; fig. 1; para. 0098) and the microwave delivery device (1; fig. 1; para. 0098), the cooling fluid having a dielectric constant greater than a dielectric constant of the cooling element (para. 0099, wherein it is disclosed that "contact plate 8 may be made of a solid material, such as a glass, a crystal such as sapphire, or a plastic"; para. 0096, wherein it is disclosed that "cooling mechanism 4 may comprise a water").

(Continued in Supplemental Box)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2008/060940

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box V

Referring to claim 10, Altshuler et al. disclose a system for coupling microwave energy into tissue (abstract; para. 0058), the system comprising: a microwave antenna (1); a fluid chamber (para. 0096) positioned between the microwave antenna (1; fig. 1; para. 0098) and the tissue (31); and a cooling plate (8) positioned between the cooling chamber (para. 0096) and the tissue (31).

Referring to claim 11, Altshuler et al. disclose a method of creating a tissue effect in a target tissue layer (abstract; para. 0058; para. 0075; table 1), comprising the steps of: irradiating the target tissue layer (6) and a first tissue layer (5) through a skin surface with electromagnetic energy having predetermined frequency and electric field characteristics (fig. 1; para. 0078; para. 0079, wherein it is disclosed that "energy source 1 may be any suitable electromagnetic radiation, EMR, source"; para. 0131), wherein the first tissue layer (5) is above the target tissue layer (6; para. 0078), the first tissue layer (5) being adjacent to a surface of the skin (fig. 1, wherein the surface of the skin is located at the interface of 5 and contact plate 8); and generating a power loss density profile (para. 0131), wherein the power loss density profile has a peak power loss density in a region of the target tissue layer (para. 0078; para. 0131; para. 0004; para. 0075).

Referring to claim 14, Altshuler et al. disclose a method of generating heat in a target tissue layer in the absence of cooling wherein the heat is sufficient to create a tissue effect in or proximate to the target tissue layer (abstract; para. 0058; para. 0075; table 1; para. 0098, wherein it is disclosed that "cooling mechanism 4 and/or contact plate 8 may be absent"), wherein the target tissue layer (6) is below a first tissue layer (5; fig. 1), the first tissue layer (5) being adjacent to a skin surface (fig. 1, wherein the surface of the skin is located at the interface of 5 and contact plate 8), the method comprising the steps of: irradiating the target tissue layer (6) and the first tissue layer (5) through the skin surface with electromagnetic energy having predetermined frequency and electric field characteristics (fig. 1; para. 0078; para. 0079, wherein it is disclosed that "energy source 1 may be any suitable electromagnetic radiation, EMR, source"; para. 0131); and generating a power loss density profile (para. 0131) wherein the power loss density profile has a peak power loss density in a region of the target tissue layer (para. 0078; para. 0131; para. 0004; para. 0075).

Referring to claim 15, Altshuler et al. disclose a method of generating a temperature profile in tissue wherein the temperature profile has a peak in a target tissue layer (para. 0075; para. 0058), wherein the target tissue layer (6) is below a first tissue layer (5; fig. 1), the first tissue layer (5) being adjacent to a skin surface (fig. 1, wherein the surface of the skin is located at the interface of 5 and contact plate 8), the method comprising the steps of: irradiating the target tissue layer (6) and the first tissue layer (5) through the skin surface with electromagnetic energy having predetermined frequency and electric field characteristics (fig. 1; para. 0078; para. 0079, wherein it is disclosed that "energy source 1 may be any suitable electromagnetic radiation, EMR, source"; para. 0131); and generating a power loss density profile (para. 0131) wherein the power loss density profile has a peak power loss density in a region of the target tissue layer (para. 0078; para 0131; para. 0004; para. 0075).

Referring to claim 16, Altshuler et al. disclose a method of generating a temperature profile in tissue in the absence of cooling wherein the temperature profile has a peak in a target tissue layer (para. 0075; para. 0058; para. 0098, wherein it is disclosed that "cooling mechanism 4 and/or contact plate 8 may be absent"), wherein the target tissue layer (6) is below a first tissue layer (5; fig. 1), the first tissue layer (5) being adjacent to a skin surface (fig. 1, wherein the surface of the skin is located at the interface of 5 and contact plate 8), the method comprising the steps of: irradiating the target tissue layer (6) and the first tissue layer (5) through the skin surface with electromagnetic energy having predetermined frequency and electric field characteristics (fig. 1; para. 0078; para. 0079, wherein it is disclosed that "energy source 1 may be any suitable electromagnetic radiation, EMR, source"; para. 0131); and generating a power loss density profile (para. 0131) wherein the power loss density profile has a peak power loss density in a region of the target tissue layer (para. 0078; para. 0131; para. 0004; para. 0075).

Referring to claim 23, Altshuler et al. disclose a method of heating a tissue structure located in or near a target tissue layer (para. 0075; para. 0058); wherein the target tissue layer (6) is below a first tissue layer (5; fig. 1), the first tissue layer (5) being adjacent a skin surface (fig. 1, wherein the surface of the skin is located at the interface of 5 and contact plate 8), the method comprising the steps of: irradiating the target tissue layer (6) and the first tissue layer (5) through the skin surface with electromagnetic energy having predetermined frequency and electric field characteristics (fig. 1; para. 0078; para. 0079, wherein it is disclosed that "energy source 1 may be any suitable electromagnetic radiation, EMR, source"; para. 0131); and generating a power loss density profile (para. 0131) wherein the power loss density profile has a peak power loss density in a region of the target tissue layer (para. 0078; para. 0131; para. 0004; para. 0075).

Claim 27 lacks novelty under PCT Article 33(2) as being anticipated by Deem et al.
Referring to claim 27, Deem et al. disclose a method of positioning tissue prior to treating the tissue using radiated electromagnetic energy (para. 0014-0015; para. 0017), the method comprising: positioning a tissue interface (60) adjacent a skin surface (102); engaging the skin surface in a tissue chamber of the tissue interface (264; figs. 7A-7B; para. 0041; para. 0080); substantially separating a layer comprising at least one layer of the skin from a muscle layer below the skin (para. 0080, wherein by sucking the skin into the chamber, the layer of skin is being separated from the muscle layer); and holding the skin surface in the tissue chamber (264; figs. 7A-7B; para. 0041; para. 0080).

(Continued in Next Supplemental Box)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2008/060940

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Previous Supplemental Box

Claims 2-5, 18, 21, 22 and 25 lack an inventive step under PCT Article 33(3) as being obvious over Knowlton in view of Richards et al.
Referring to claim 2, Knowlton teaches the system as shown in claim 1 above. Knowlton does not teach wherein the microwave signal has a frequency in the range of between about 4 GHz and about 10 GHz.
However, Richards et al. teaches a microwave applicator comprising a microwave signal having a frequency in the range of between about 4 GHz and about 10 GHz (claim 8; col. 17, lines 45-47).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Knowlton wherein the microwave signal has a frequency in the range of between about 4 GHz and about 10 GHz as taught by Richards et al., for the purpose of providing an optimal frequency for heating tissue at greater depths.

Referring to claim 3, Knowlton teaches the system as shown in claim 2 above. Knowlton does not teach wherein the microwave signal has a frequency in the range of between about 5 GHz and about 6.5 GHz.
However, Richards et al. teaches a microwave applicator comprising a microwave signal having a frequency in the range of between about 5 GHz and about 6.5 GHz (claim 8; col. 17, lines 45-47).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Knowlton wherein the microwave signal has a frequency in the range of between about 5 GHz and about 6.5 GHz as taught by Richards et al., for the purpose of providing an optimal frequency for heating tissue at greater depths.

Referring to claim 4, Knowlton teaches the system as shown in claim 3 above. Knowlton does not teach wherein the microwave signal has a frequency of about 5.8 GHz.
However, Richards et al. teaches a microwave applicator comprising a microwave signal having a frequency of about 5.8 GHz (claim 8; col. 17, lines 45-47). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Knowlton wherein the microwave signal has a frequency of about 5.8 GHz as taught by Richards et al., for the purpose of providing an optimal frequency for heating tissue at greater depths.

Referring to claim 5, Knowlton teaches the system as shown in claim 1 above. Knowlton does not teach wherein the microwave antenna comprises an antenna configured to radiate electromagnetic radiation polarized such that an E-field component of the electromagnetic radiation is substantially parallel to an outer surface of the tissue.
However, Richards et al. teaches a microwave applicator comprising a microwave antenna including an antenna configured to radiate electromagnetic radiation polarized such that an E-field component of the electromagnetic radiation is substantially parallel to an outer surface of the tissue (col. 1, lines 62-66; col. 6, lines 27-29, wherein the patch is parallel to the surface of the tissue therefore the e-field component is parallel to the surface of the tissue).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Knowlton wherein the microwave antenna comprises an antenna configured to radiate electromagnetic radiation polarized such that an E-field component of the electromagnetic radiation is substantially parallel to an outer surface of the tissue as taught by Richards et al., for the purpose of providing an optimal orientation for the frequency for heating tissue at greater depths.

Referring to claim 18, Knowlton teaches a method of creating a lesion (para. 0225; para. 0015) in the skin wherein the skin has at least an external surface (fig. 1; para. 0103), a first layer (9'; fig. 1) below the external surface (fig. 1; para. 0103) and a second layer (9"), the method comprising the steps of: positioning a device adapted to radiate electromagnetic energy adjacent the external surface (12; para. 0108; para. 0121); radiating electromagnetic energy from the device (para. 0108; para. 0121). Knowlton does not teach the method comprising the microwave energy having an electric field component which is substantially parallel to a region of the external surface; and generating a standing wave pattern in the first layer, the standing wave pattern having a constructive interference peak in the first layer, wherein a distance from the constructive interference peak to the skin surface is greater than a distance from the constructive interference peak to an interface between the first layer and the second layer.
However, Richards et al. teaches a microwave applicator comprising microwave energy having an electric field component which is substantially parallel to a region of the external surface (col. 1, lines 62-66; col. 6, lines 27-29, wherein the patch is parallel to the surface of the tissue therefore the e-field component is parallel to the surface of the tissue); and generating a standing wave pattern in the first layer (col. 1, lines 62-66; abstract; col. 2, lines 24-36), the standing wave pattern having a constructive interference peak in the first layer (col. 2, lines 24-36), wherein a distance from the constructive interference peak to the skin surface is greater than a distance from the constructive interference peak to an interface between the first layer and the second layer (col. 2, lines 24-36).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Knowlton to comprise the microwave energy having an electric field component which is substantially parallel to a region of the external surface; and generating a standing wave pattern in the first layer, the standing wave pattern having a constructive interference peak in the first layer, wherein a distance from the constructive interference peak to the skin surface is greater than a distance from the constructive interference peak to an interface between the first layer and the second layer as taught by Richards et al., for the purpose of providing an optimal frequency orientation and pattern for heating tissue at greater depths.

(Continued in Next Supplemental Box)

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Previous Supplemental Box

Referring to claim 21, Knowlton teaches a method of creating a lesion in a dermal layer of the skin (para. 0225; para. 0015) wherein the skin has at least a dermal layer and a subdermal layer (fig. 1; para. 0103), the method comprising the steps of: positioning a device adapted to radiate microwave energy adjacent an external surface of the skin (12; para. 0108; para. 0121). Knowlton does not teach the method comprising radiating microwave energy having an electric field component which is substantially parallel to a region of the external surface of the skin above the dermal layer, wherein the microwave energy has a frequency which generates a standing wave pattern in the dermal layer, the standing wave pattern having a constructive interference peak in the dermal layer proximal to an interface between the dermal layer and the subdermal layer.
However, Richards et al. teaches a microwave applicator comprising a process of radiating microwave energy having an electric field component which is substantially parallel to a region of the external surface of the skin above the dermal layer (col. 1, lines 62-66; col. 6, lines 27-29, wherein the patch is parallel to the surface of the tissue therefore the e-field component is parallel to the surface of the tissue), wherein the microwave energy has a frequency which generates a standing wave pattern in the dermal layer (col. 1, lines 62-66; abstract; col. 2, lines 24-36), the standing wave pattern having a constructive interference peak in the dermal layer proximal to an interface between the dermal layer and the subdermal layer (col. 2, lines 24-36).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Knowlton to comprise radiating microwave energy having an electric field component which is substantially parallel to a region of the external surface of the skin above the dermal layer, wherein the microwave energy has a frequency which generates a standing wave pattern in the dermal layer, the standing wave pattern having a constructive interference peak in the dermal layer proximal to an interface between the dermal layer and the subdermal layer as taught by Richards et al., for the purpose of providing an optimal frequency orientation and pattern for heating tissue at greater depths.

Referring to claim 22, Knowlton teaches a method of creating a lesion in a dermal layer of the skin (para. 0225; para. 0015) wherein the skin has at least a dermal layer and a subdermal layer (fig. 1; para. 0103), the method comprising the steps of: positioning a device adapted to radiate microwave energy adjacent an external surface of the skin (12; para. 0108; para. 0121); and heating the lower portion of the dermal region using the radiated microwave energy to create the lesion (para. 0225; para. 0015). Knowlton does not teach the method comprising radiating microwave energy having an electric field component which is substantially parallel to a region of the external surface of the skin above the dermal layer, wherein the microwave energy has a frequency which generates a standing wave pattern in the dermal layer, the standing wave pattern having a constructive interference peak in the dermal layer proximal to an interface between the dermal layer and the subdermal layer.
However, Richards et al. teaches a microwave applicator comprising a process of radiating microwave energy having an electric field component which is substantially parallel to a region of the external surface of the skin above the dermal layer (col. 1, lines 62-66; col. 6, lines 27-29, wherein the patch is parallel to the surface of the tissue therefore the e-field component is parallel to the surface of the tissue), wherein the microwave energy has a frequency which generates a standing wave pattern in the dermal layer (col. 1, lines 62-66; abstract; col. 2, lines 24-36), the standing wave pattern having a constructive interference peak in the dermal layer proximal to an interface between the dermal layer and the subdermal layer (col. 2, lines 24-36).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Knowlton to comprise radiating microwave energy having an electric field component which is substantially parallel to a region of the external surface of the skin above the dermal layer, wherein the microwave energy has a frequency which generates a standing wave pattern in the dermal layer, the standing wave pattern having a constructive interference peak in the dermal layer proximal to an interface between the dermal layer and the subdermal layer as taught by Richards et al., for the purpose of providing an optimal frequency orientation and pattern for heating tissue at greater depths.

Referring to claim 25, Knowlton teaches a method of raising the temperature of at least a portion of a tissue structure located below an interface between a dermal layer and a subdermal layer of skin (para. 0099-0100), wherein the dermal layer has an upper portion adjacent an external surface of the skin and a lower portion adjacent a subdermal region of the skin (fig. 1; para. 0103), the method comprising the steps of: positioning a device adapted to radiate microwave energy adjacent the external surface of the skin (12; para. 0108; para. 0121); creating a lesion in the lower portion of the dermal region by heating tissue in the lower portion of the dermal region using the radiated microwave energy (para. 0099; para. 0225; para. 0015); removing heat from the skin surface and at least a portion of the upper portion of the dermal layer to prevent the lesion from spreading into the upper portion of the dermal layer (para. 0111); and ceasing the radiating after a first predetermined time (para. 0171), the predetermined time being sufficient to raise the temperature of the tissue structure (para. 0258; para. 0225; para. 0015). Knowlton does not teach the method comprising radiating microwave energy having an electric field component which is substantially parallel to a region of the external surface above the dermal layer, wherein the microwave energy has a frequency which generates a standing wave pattern in the dermal layer, the standing wave pattern having a constructive interference peak in the lower portion of the dermal layer.
However, Richards et al. teaches a microwave applicator comprising a process of radiating microwave energy having an electric field component which is substantially parallel to a region of the external surface above the dermal layer (col. 1, lines 62-66; col. 6, lines 27-29, wherein the patch is parallel to the surface of the tissue therefore the e-field component is parallel to the surface of the tissue), wherein the microwave energy has a frequency which generates a standing wave pattern in the dermal layer (col. 1, lines 62-66; abstract; col. 2, lines 24-36), the standing wave pattern having a constructive interference peak in the lower portion of the dermal layer (col. 2, lines 24-36).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Knowlton to comprise radiating microwave energy having an electric field component which is substantially parallel to a region of the external surface above the dermal layer, wherein the microwave energy has a frequency which generates a standing wave pattern in the dermal layer, the standing wave pattern having a constructive interference peak in the lower portion of the dermal layer as taught by Richards et al., for the purpose of providing an optimal frequency orientation and pattern for heating tissue at greater depths.

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Claims 6 and 13 lack an inventive step under PCT Article 33(3) as being obvious over Knowlton in view of Altshuler et al.
Referring to claim 6, Knowlton teaches the system as shown in claim 1 above. Knowlton does not teach wherein the tissue comprises a first layer and a second layer, the second layer below the first layer, wherein the controller is configured such that the system delivers energy such that a peak power loss density profile is created in the second layer.
However, Altshuler et al. teaches a microwave apparatus comprising a tissue comprising a first layer (5) and a second layer (6), the second layer below the first layer (fig. 1), wherein the controller is configured such that the system delivers energy such that a peak power loss density profile is created in the second layer (para. 0078; para. 0131; para. 0004; para. 0075).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Knowlton wherein the tissue comprises a first layer and a second layer, the second layer below the first layer, wherein the controller is configured such that the system delivers energy such that a peak power loss density profile is created in the second layer as taught by Altshuler et al., for the purpose of providing the maximum heating at the selected tissue depth.

Referring to claim 13, Knowlton teaches a method of generating heat in a target tissue layer wherein the heat is sufficient to create a lesion in or proximate to the target tissue layer (para. 0225; para. 0015), wherein the target tissue layer (9"; para. 0103) is below a first tissue layer (9'; para. 0103), the first tissue layer (9'; fig. 1; para. 0103) being adjacent to a skin surface (fig. 1; para. 0103), the method comprising the steps of: irradiating the target tissue layer (9"; para. 0103; para. 0099) and the first tissue layer (9'; para. 0103) through the skin surface (fig. 1; para. 0103) with electromagnetic energy having predetermined frequency and electric field characteristics (para. 0099; para. 0108; para. 0151; para. 0121; claim 7; para. 0261). Knowlton does not teach the method comprising generating a power loss density profile wherein the power loss density profile has a peak power loss density in a region of the target tissue layer.
However, Altshuler et al. teaches a microwave apparatus comprising a proces of generating a power loss density profile (para. 0131) wherein the power loss density profile has a peak power loss density in a region of the target tissue layer (para. 0078; para. 0131; para. 0004; para. 0075). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Knowlton generating a power loss density profile wherein the power loss density profile has a peak power loss density in a region of the target tissue layer as taught by Altshuler et al., for the purpose of providing the maximum heating at the selected tissue depth.

Claim 8 lacks an inventive step under PCT Article 33(3) as being obvious over Deem et al. in view of Altshuler et al.
Referring to claim 8, Deem et al. teaches an apparatus for delivering microwave energy to a target region in tissue (para. 0014-0015; para. 0017), the apparatus comprising: a tissue interface having a tissue acquisition chamber (264; figs. 7A-7B; para. 0041; para. 0080); and a microwave energy delivery device (para. 0017; 204) having a microwave antenna (para. 0017; para. 0061). Deem et al. does not teach the apparatus comprising a cooling element having a cooling plate.
However, Altshuler et al. teaches a microwave apparatus comprising a cooling element (4) having a cooling plate (8).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Deem et al. to comprise a cooling element having a cooling plate as taught by Altshuler et al., for the purpose of providing the maximum heating at the selected tissue depth with optimal cooling at the surface of the skin.

Claims 12, 17 and 20 lack an inventive step under PCT Article 33(3) as being obvious over Altshuler et al. in view of Knowlton.
Referring to claim 12, Altshuler et al. teaches a method of creating a tissue effect in a target tissue layer in the absence of cooling (abstract; para. 0058; para. 0075; table 1; para. 0098, wherein it is disclosed that "cooling mechanism 4 and/or contact plate 8 may be absent"), wherein the target tissue layer (6) is below a first tissue layer (5; fig. 1), the first tissue layer (5) being adjacent to a skin surface (fig. 1, wherein the surface of the skin is located at the interface of 5 and contact plate 8), the method comprising the steps of: irradiating the target tissue layer (6) and a first tissue layer (5) through a skin surface with electromagnetic energy having predetermined frequency and electric field characteristics (fig. 1; para. 0078; para. 0079, wherein it is disclosed that "energy source 1 may be any suitable electromagnetic radiation, EMR, source"; para. 0131), wherein the first tissue layer (5; fig. 1; para. 0078) is above the target tissue layer (6; fig. 1: para. 0078), the first tissue layer (5) being adjacent to a surface of the skin (fig. 1, wherein the surface of the skin is located at the interface of 5 and contact plate 8); and generating a power loss density profile (para. 0131), wherein the power loss density profile has a peak power loss density in a region of the target tissue layer (para. 0078; para. 0131; para. 0004; para. 0075). Altshuler et al. does not teach wherein the tissue effect comprises creating a lesion in a target tissue layer.
However, Knowlton teaches a microwave energy system wherein tissue effect comprises creating a lesion in a target tissue layer (para. 0225; para. 0015). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Altshuler et al. wherein the tissue effect comprises creating a lesion in a target tissue layer as taught by Knowlton, for the purpose of providing the creation of a thermal lesion for the desired therapeutic effect.

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Referring to claim 17, Altshuler et al. teach a method of creating a tissue effect (abstract; para. 0058; para. 0075; table 1) in a first layer of tissue (5; fig. 1; para. 0077-0078), the first layer having an upper portion adjacent an external surface of the skin (fig. 1, wherein the upper surface of the skin 5 is located at the interface of 5 and contact plate 8) and a lower portion adjacent a second layer of the skin (fig. 1, wherein the lower portion is adjacent a second layer 6; para. 0077-0078), the method comprising the steps of: exposing the external surface of the skin to microwave energy having a predetermined power, frequency, and electric field orientation (fig. 1; para. 0077 -0078; para. 0079, wherein it is disclosed that "energy source 1 may be any suitable electromagnetic radiation, EMR, source"; para. 0131); and generating an energy density profile having a peak in the lower portion of the first layer (para. 0077-0078; para. 0131; para. 0004; para. 0075). Altshuler et al. does not teach a method of creating a lesion in a first layer of tissue, the method comprising continuing to expose the external surface of the skin to the microwave energy for a time sufficient to create a lesion, wherein the lesion begins in the peak energy density region.
However, Knowlton teaches a microwave energy system comprising a process of creating a lesion in a first layer of tissue (para. 0225; para. 0015), the method comprising continuing to expose the external surface of the skin to the microwave energy for a time sufficient to create a lesion, wherein the lesion begins in the peak energy density region (para. 0099; para. 0104; para. 0225; para. 0015; para. 0237).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Altshuler et al. to comprise a method of creating a lesion in a first layer of tissue, the method comprising continuing to expose the external surface of the skin to the microwave energy for a time sufficient to create a lesion, wherein the lesion begins in the peak energy density region as taught by Knowlton, for the purpose of providing the creation of a thermal lesion for the desired therapeutic effect.

Referring to claim 20, Alstshuler et al. teach a method of creating a tissue effect (abstract; para. 0058; para. 0075; table 1) in a dermal layer of the skin (5; fig. 1; para. 0077-0078), the dermal layer having an upper portion adjacent an external surface of the skin (fig. 1, wherein the upper surface of the skin 5 is located at the interface of 5 and contact plate 8) and a lower portion adjacent a subdermal layer of the skin (fig. 1, wherein the lower portion is adjacent a second layer 6; para. 0077-0078), the method comprising the steps of: exposing the external surface to microwave energy having a predetermined power, frequency, and electric field orientation (fig. 1; para. 0077-0078; para. 0079, wherein it is disclosed that "energy source 1 may be any suitable electromagnetic radiation, EMR, source"; para. 0131); and generating a peak energy density region in the lower portion of the dermal layer (para. 0078; para. 0131; para. 0004; para. 0075).
Altshuler et al. does not teach a method of creating a lesion in a dermal layer of the skin, the method comprising continuing to radiate the skin with the microwave energy for a time sufficient to create a lesion, wherein the lesion begins in the peak energy density region.
However, Knowlton teaches a microwave energy system comprising a method of creating a lesion in a dermal layer of the skin (para. 0225; para. 0015), the method comprising continuing to radiate the skin with the microwave energy for a time sufficient to create a lesion, wherein the lesion begins in the peak energy density region (para. 0099; para. 0104; para. 0225; para. 0015; para. 0237).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Altshuler et al. to comprise a method of creating a lesion in a dermal layer of the skin, the method comprising continuing to radiate the skin with the microwave energy for a time sufficient to create a lesion, wherein the lesion begins in the peak energy density region as taught by Knowlton, for the purpose of providing the creation of a thermal lesion for the desired therapeutic effect.

Claim 19 lacks an inventive step under PCT Article 33(3) as being obvious over Altshuler et al. in view of Richards et al.
Referring to claim 19, Altshuler et al. teach a method of creating a temperature gradient in the skin (para. 0075; para. 0058) wherein the skin has at least an external surface (fig. 1, wherein the surface of the skin is located at the interface of 5 and contact plate 8), a first layer (5) below the external surface (fig. 1, wherein the surface of the skin is located at the interface of 5 and contact plate 8) and a second layer (6), the method comprising the steps of: positioning a device adapted to radiate electromagnetic energy adjacent the external surface (fig. 1; para. 0078; para. 0079, wherein it is disclosed that "energy source 1 may be any suitable electromagnetic radiation, EMR, source"; para. 0131); radiating electromagnetic energy from the device (fig. 1; para. 0078; para. 0079, wherein it is disclosed that "energy source 1 may be any suitable electromagnetic radiation, EMR, source"; para. 0131). Altshuler et al. does not teach the method comprising the microwave energy having an electric field component which is substantially parallel to a region of the external surface; and generating a standing wave pattern in the first layer, the standing wave pattern having a constructive interference peak in the first layer, wherein a distance from the constructive interference peak to the skin surface is greater than a distance from the constructive interference peak to an interface between the first layer and the second layer.
However, Richards et al. teaches the method comprising the microwave energy having an electric field component which is substantially parallel to a region of the external surface (col. 1, lines 62-66; col. 6, lines 27-29, wherein the patch is parallel to the surface of the tissue therefore the e-field component is parallel to the surface of the tissue); and generating a standing wave pattern in the first layer (col. 1, lines 62-66; abstract; col. 2, lines 24-36), the standing wave pattern having a constructive interference peak in the first layer (col. 2, lines 24-36), wherein a distance from the constructive interference peak to the skin surface is greater than a distance from the constructive interference peak to an interface between the first layer and the second layer (col. 2, lines 24-36).
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Altshuler et al. to comprise the microwave energy having an electric field component which is substantially parallel to a region of the external surface; and generating a standing wave pattern in the first layer, the standing wave pattern having a constructive interference peak in the first layer, wherein a distance from the constructive interference peak to the skin surface is greater than a distance from the constructive interference peak to an interface between the first layer and the second layer as taught by Richards et al., for the purpose of providing an optimal frequency orientation and pattern for heating tissue at greater depths.

Claims 1-27 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.